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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,081	11/13/2003	David H. Coy	00537-164003	7933
26161	7590	10/06/2004	EXAMINER	
FISH & RICHARDSON PC			DELACROIX MUIRHEI, CYBILLE	
225 FRANKLIN ST			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	

1614

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,081	COY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to the preliminary amendment received Nov. 13, 2003.

Claims 13-17 are cancelled. No new claims are added.

Claims 1-12, 18-31 are presented for prosecution on the merits.

Priority

Applicant's claim for priority under 35 U.S.C. 120 based upon previously filed applications is noted. However, the status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Information Disclosure Statement(s)

Applicant's Information Disclosure Statement received Nov. 13, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

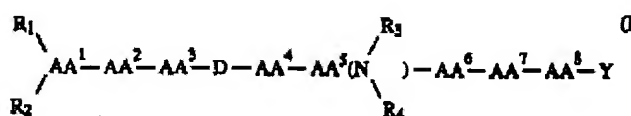
Claim Rejection(s)—35 USC 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Coy et al., 5,462,926.

Coy et al. disclose somatostatin analogs represented by Formula (I):

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wherein

AA¹ is the D- or L-isomer of an aromatic α -amino acid;AA² is the D- or L-isomer of Cys;AA³ is F-Phe, Phe, or X-Phe in which X is halogen, NO₂, CH₃, or OH;AA⁴ is Trp or an aromatic α -amino acid;AA⁵ is Lys or Orn;AA⁶ is Thr or Ser;AA⁷ is the D- or L-isomer of Cys;AA⁸ is the D- or L-isomer selected from the group consisting of an aromatic α -amino acid;

wherein substituents R1-R4 are as defined in col. 3, line 61 to col. 4, line 15. Specific

species disclosed by Coy et al. are **H₂-D-Nal-D-Cys-Tyr-D-Trp-Lys-Thr-Cys-Nal-NH₂** and

H₂-D-Nal-D-Cys-Tyr-D-Trp-Lys-Val-Cys-Nal-NH₂. Please see col. 4, line 25 and claim 13, line 29.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 2, 8, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Bass et al., 5,846,934 (already of record).

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Bass et al. disclose the invention substantially as claimed. Specifically, Bass discloses octapeptide compounds that are somatostatin antagonists. Said compounds read on Applicant's generic structure in claim 1 and on the species set forth in claim 12. Please see col. 1, lines 30-33; col. 2, lines 29-58; Table 1 in col. 8; claims 1-20.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 8, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coy et al., 5,597,894 in view of Bass et al. (both references already of record).

Coy et al. teach the following somatostatin analog:

D β -Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr(NH₂) . Please see col. 3, lines 27-26.

Coy et al. do not disclose modification of the Cys at position 2 into a D-amino acid. However, the Examiner refers to Bass et al., which studies the identification and characterization of somatostatin antagonists, wherein said antagonists contain a core structure of DL-cysteine pair at positions 2 and 7. Please see the abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analog of Coy et al. to have a D-Cys at position 2 because Bass discloses that somatostatin analogues with a D-Cys(2) and L-Cys(7) "display potent antagonist properties." Please see page 713, second column, third full paragraph.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 and 18-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9 of U.S. Patent No. 6,262,229. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in the claims of USPN '229. That is, the claims of USPN '229 fall entirely within the scope of the claims of the instant application. In other words, the claims of the instant application are anticipated by claims 1-3, 9 of USPN '229. Specifically, the claims of USPN '229 recite substantially identical somatostatin compounds as those claimed in the instant application, wherein the claims limit the moieties for substituents A1-A4 and A6-A8 resulting in a subgenus of the compounds claimed in the instant application.

5. Claims 1-12 and 18-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,703,481. An obviousness-type double patenting rejection is appropriate

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where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to all that is recited in claims 1-5 of USPN '481. That is, the claims of USPN '481 fall entirely within the scope of the claims of the instant application. In other words, the claims of the instant application are anticipated by claims 1-5 of USPN '481. Specifically, the claims of USPN '481 recite substantially identical somatostatin compounds as those claimed in the instant application, wherein claim 1 provides a subgeneric formula of the compounds claimed in the instant application.

Conclusion

Claims 1-12, 18-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

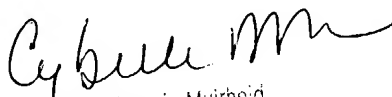
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone

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number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Oct. 1, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600